EXHIBIT 1

FILED IN OFFICE

IN THE CIRCUIT COURT OF BULLOCK COUNTY, ALABAMA

AUG 3 1 2005

CLERK-REGISTER, OBELGSK 29., ALA.

WILLIAM RANDOLPH HALL, SR., as the Administrator of the Estate of WILLIAM RANDOLPH HALL, JR. Plaintiff,

CIVIL NO. <u>CV- JUS. 98</u>

vs.

**
PFIZER INC., a Delaware Corporation; **

AND TIFFANY GUCKENBERY
And fictitious Defendants
A, B, C and D being those persons, firms
or corporations whose actions, inactions,
fraudulent suppression, fraud, scheme to
defraud and/or other wrongful conduct
caused or contributed to the Plaintiff's
injuries and damages, and whose true
names and identities are presently
unknown to the Plaintiff but will be
substituted by amendment when

TRIAL BY JURY IS REQUESTED

Defendants.

ascertained,

COMPLAINT

COMES NOW William Randolph Hall, Sr., (hereinafter "Plaintiff"), as the Administrator of the Estate of William Randolph Hall, Jr., deceased, in an action against Pfizer, Inc., Pharmacia Corporation, Monsanto Company, G.D. Searle, LLC., Robert Vandelune, Samuel Klement; Jamie Peacock; Ben McClurkin, Rod McWhorter and Tiffany Guckenbery (hereinafter "Defendants"), and for Plaintiff's cause of action against the Defendants states as follows:

Statement Of The Parties

- 1. This is a civil action brought by Plaintiff, William Randolph Hall, Sr., on behalf of William Randolph Hall, Jr., deceased, for injuries resulting in a heart attack and death.

 Plaintiff's Decedent was prescribed and used the prescription medication Celebrex (Celecoxib).

 This action seeks monetary damages for the wrongful death caused by Celebrex and ingested by William Randolph Hall, Jr., the deceased.
- 2. Plaintiff, William Randolph Hall, Sr., is over the age of 19 years and is currently a resident of Bullock County, Alabama. Plaintiff is the legal representative of the estate of his Decedent.
- Defendant G. D. Searle LLC (hereinafter "Searle") was a subsidiary of Pharmacia Corporation and is, upon information, knowledge and belief an Illinois Corporation. At all times relevant hereto, Searle, as a subsidiary of Pharmacia Corporation, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Defendant Searle is licensed and registered to do business in the State of Alabama. Defendant Searle can be served at its principle place of business: G. D. Searle, LLC; 4901 Searle Parkway; Skokie, Illinois 60077.
- 4. Defendant Pharmacia Corporation (hereinafter "Pharmacia") is a Delaware Corporation with its principal place of business in New Jersey. At all times relevant to this action, Pharmacia was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Defendant Pharmacia is licensed and registered to do business in the State of Alabama. Defendant Pharmacia can be served at its principle place of business: Pharmacia Corporation; 100 U.S. Highway 206 North; Peapack, New Jersey 07977.
 - 5. Defendant Monsanto Company (hereinafter "Monsanto") was the parent

corporation of Pharmacia and is a Delaware Corporation. At all times relevant hereto, Monsanto, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Defendant Monsanto is licensed and registered to do business in the State of Alabama. Defendant Monsanto can be served at its principle place of business: Monsanto Company; 800 North Lindbergh Boulevard; St. Louis, Missouri 63167.

- 6. Defendant Pfizer, Inc. (hereinafter "Pfizer") is a Delaware corporation with its principal place of business in New York. At all times relevant hereto, Pfizer was in the business of marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib).

 Defendant Pfizer is licensed and registered to do business in the State of Alabama and may be served through its registered agent at Pfizer, Inc., c/o The Corporation Company; 2000 Interstate Park Drive, Suite 204; Montgomery, Alabama 36109.
- 7. Defendant Robert Vandelune, at all times material hereto, was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the course and scope of his employment with the Pfizer Defendants. Upon information and belief, Defendant Vandelune is a resident of Alabama and, at all times material hereto, was in the business of marketing, selling and distributing Celebrex. Defendant Vandelune can be served at his home address: 1206 Rampart Road, Dothan, Alabama 36303.
- 8. Defendant Samuel Klement at all times material hereto was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the course and scope of his employment with the Pfizer Defendants. Upon information and belief, Defendant Klement is a resident of Alabama and, at

all times material hereto, was in the business of marketing, selling and distributing Celebrex.

Defendant Klement can be served at his home address: 1101 Hillbrook Road, Dothan, Alabama 36303-1977.

- 9. Defendant Jamie Peacock at all times material hereto was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the course and scope of her employment with the Pfizer Defendants. Upon information and belief, Defendant Peacock is a resident of Alabama and, at all times material hereto, was in the business of marketing selling and distributing Celebrex. Defendant Peacock can be served at his home address: 1804 Choctaw, Dothan, Alabama 36303.
- 10. Defendant Ben McClurkin, at all times material hereto, was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the course and scope of his employment with the Pfizer Defendants. Upon information and belief, Defendant McClurkin is a resident of Alabama and, at all times material hereto, was in the business of marketing, selling and distributing Celebrex. Defendant McClurkin can be served at his home address: 105 Brentwood Drive, Dothan, Alabama 36303.
- Defendant Rod McWhorter, at all times material hereto, was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the course and scope of his employment with the Pfizer Defendants. Upon information and belief, Defendant McWhorter is a resident of Alabama and, at all times material hereto, was in the business of marketing, selling and distributing Celebrex. Defendant McWhorter can be served at his home address: 109 Hampton Avenue, Troy, Alabama 36081.

- 12. Defendant Titfany Guckenberg, at all times material hereto, was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the course and scope of her employment with the Pfizer Defendants. Upon information and belief, Defendant Guckenberg is a resident of Alabama and, at all times material hereto, was in the business of marketing, selling and distributing Celebrex. Defendant Guckenbery can be served at her home address: 113 Westchester Drive, Dothan, Alabama 36301.
- 13. Fictitious Defendants A, B, C & D, are other legal persons (including retailers, pharmacies, sales representatives and manufacturers) who manufactured, labeled, advertised, marketed, promoted, sold and/or distributed Celebrex (Celecoxib) in Alabama.
- 14. Personal jurisdiction and subject matter jurisdiction are appropriate in this court as to all Defendants, as all Defendants have done business in Bullock County, Alabama, either directly, or by agent, and have thus submitted themselves to the jurisdiction of this Court.
- The Plaintiff's claims accrued in whole or in part in Bullock County, Alabama and the Plaintiff resides in Bullock County. Plaintiff's Decedent ingested celebrex (celecoxib) in and while residing in Bullock County, Alabama. Some of these Defendants are foreign corporations, which have been and are currently engaged in business, directly or by authorized agent, in Bullock County, Alabama. Upon information and belief, the Sales Representatives are individuals who, at all times material hereto, transacted business in Bullock City, Alabama. Venue and jurisdiction are therefore proper. The claims of Plaintiff herein satisfy the jurisdictional amount of this court.
- 16. Defendants Robert Vandelune, Samuel Klement, Jamie Peacock, Ben McClurkin, Rod McWhorter and Tiffany Guckenbery (hereinafter collectively referred to as "Sales

Representatives") and the Pfizer Defendants marketed and distributed this drug in Bullock County, Alabama. Defendants encouraged the use of this drug to improper customers, misrepresented the safety and effectiveness of this drug and concealed or understated its dangerous side effects in Bullock County, Alabama. These Defendants aggressively marketed this drug directly to the consuming public through the use of various marketing mediums, including, but not limited to, print and television advertisements in Bullock County, Alabama.

- Based on information and belief, the Sales Representatives called on physicians, 17. including Plaintiff's physicians on numerous occasions, at which times they presented fraudulent information regarding the safety and efficacy of Celebrex and its harmful side effects, and/or fraudulently suppressed material information regarding the safety and efficacy of Celebrex and its harmful side effects, and/or placed Celebrex in the stream of commerce by providing Plaintiff's physician(s) samples of the drug Celebrex.
- At all times material hereto, the Pfizer Defendants and the Defendant Sales 18. Representatives advertised, marketed, and/or promoted Celebrex to Plaintiff's Decedent's prescribing physicians, utilizing information known to fraudulently represent the safety and efficacy of Celebrex. They failed to warn of the known dangers and adverse events associated with the use of the drug Celebrex.
- 19. At all times material hereto, the Defendant Sales Representatives placed Celebrex in the stream of commerce by distributing to physicians, including Plaintiff's physician, numerous samples of Celebrex at varying doses.
- At all times relevant hereto, the Defendants actually knew of the defective nature 20. of their product as herein set forth, yet continued to design, manufacture, market, distribute and sell their product in Bullock County, Alabama. Defendants' conduct exhibits an entire lack of

care as to the safety of this product and a conscious disregard for the foreseeable harm caused by this product in Bullock County, Alabama.

Statement of the Facts

- At all times relevant hereto, Defendants were engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the pharmaceutical drug Celebrex (Celecoxib) throughout the United States.
- 22. Celebrex is a pharmaceutical treatment for musculoskeletal joint pain associated with osteoarthritis, among other maladies. Defendants did manufacture, design, package, market and distribute this drug. Defendants encouraged the use of this drug to improper customers, misrepresented the safety and effectiveness of this drug and concealed or understated its dangerous side effects. These Defendants aggressively marketed this drug directly to the consuming public, although only available through prescription, through the use of various marketing mediums, including, but not limited to, print and television advertisements. These Defendants did this to increase sales and profits.
- 23. Defendants, at all times relevant hereto, knew of the defective nature of their product as herein set forth, yet continued to design, manufacture, market, distribute and sell their product so as to maximize sales and profits at the expense of the general public's health and safety, in conscious disregard of the foreseeable harm caused by this product. Defendants' conduct exhibits such an entire lack of care as to establish that their actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to the Plaintiff's Decedent's individual rights, and hence punitive damages are appropriate.
- 24. William Randolph Hall, Jr. was 39 years old on or about December 23, 2004, when he died from a heart attack due to his use of Celebrex (Celecoxib).

- This Complaint seeks redress for the wrongful death of William Randolph Hall, 25. Jr., resulting from the use of Celebrex (Celecoxib), manufactured and sold by the Defendants.
- The damages sought herein are the direct and proximate result of Defendants' 26. wrongful conduct in connection with design, testing, inspection, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the prescription drug Celebrex (Celecoxib).
- 27. Had Defendants properly disclosed the risks associated with using Celebrex (Celecoxib), Plaintiff's Decedent would not have taken it for treatment of pain.
- 28. This action is being brought in the Circuit Court of Bullock County, because the amount of recovery sought exceeds the jurisdictional levels of all lower courts.
- 29. Defendants, directly or indirectly, negligently designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Celebrex (Celecoxib).
- 30. At all times material hereto, Defendants had a duty to users and/or consumers of Celebrex (Celecoxib), including Plaintiff, to exercise reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Celebrex (Celecoxib).
- 31. Defendants breached that duty and were negligent in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Celebrex (Celecoxib) in that Celebrex (Celecoxib) was defective when put on the market by Defendants; that with such defect, Celebrex (Celecoxib) was reasonably certain to be dangerous when put to normal use; and that Defendants failed to use reasonable care in designing or making Celebrex (Celecoxib) or in inspecting it for defects. Specifically, Defendants breached their duty by, among other things:

- Failing to include adequate warnings that would alert the medical, a. pharmaceutical and/or scientific communities, and users and/or consumers of the drug. including Plaintiff, to the potential risks and serious side effects of the drug;
- Failing to adequately and properly test and inspect the drug before placing the drug on the market;
- Failing to conduct sufficient testing and inspection of the drug which, if c. properly performed, would have shown that the drug had serious side effects, including, but not limited to, heart attack, stroke, life threatening allergic and/or skin reactions and/or death.
- Failing to adequately warn the medical, pharmaceutical and/or scientific d. communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and other serious side effects associated with the drug, including, but not limited to, heart attack, stroke, life threatening allergic and/or skin reactions and/or death;
- Failing to provide adequate post-marketing warnings or instructions after e. Defendants knew or should have known of the significant risks associated with the use of the drug;
- f. Failing to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug;
- Encouraging misuse and overuse of this drug while failing to disclose the deadly side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff's Decedent, in order to make a profit from sales.
- 32. Defendants knew or should have known that Celebrex (Celecoxib) caused unreasonably dangerous risks and serious side effects which users of the drug, including

Plaintiff's Decedent, were not aware. Defendants nevertheless advertised, promoted, marketed, sold, distributed and/or supplied Celebrex (Celecoxib) knowing that there were safer and more appropriate methods for pain relief.

- 33. As a direct, legal, proximate and producing result of the negligence of Defendants, Plaintiff's Decedent sustained substantial injuries including, among other things, a heart attack resulting in death.
- 34. As a direct, legal, proximate and producing result of the negligence of Defendants, Plaintiff's Decedent died.
- 35. At all times material hereto, Celebrex (Celecoxib) was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:
 - When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose as intended to be used, thereby subjecting users of the drug, including Plaintiff's Decedent, to risks which exceeded the benefits of the drug;
 - The drug was insufficiently tested; b.
 - The drug caused harmful side effects that outweighed any potential utility; c.
 - d. The drug was not accompanied by adequate labeling or instructions for use to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, of the potential risks and serious side effects associated with its use;
 - In light of the potential and actual risk of harm associated with the drug's e. use, a reasonable person who had actual knowledge of this potential and actual risk of

harm would have concluded that Celebrex (Celecoxib) should not have been marketed in that condition.

- 36. At all times during which the drug Celebrex (Celecoxib) was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United States, including Plaintiff's Decedent, without substantial change in the defective and unreasonably dangerous condition in which it was sold.
- At all times, Plaintiff's Decedent used Celebrex (Celecoxib) for its intended or 37. reasonably foreseeable purpose.
- 38. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Celebrex (Celecoxib), Plaintiff's Decedent sustained substantial injuries including, among other things, a heart attack, resulting in death.
- Celebrex (Celecoxib) was defective and unreasonably dangerous when it left the 39. possession of Defendants in that it contained warnings insufficient to alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, of the dangerous risks and reactions associated with Celebrex (Celecoxib) when used for its intended or reasonably foreseeable purpose. Those dangerous risks and reactions included, but were not limited to, heart attack, stroke, life threatening allergic and/or skin reactions, other serious and life threatening side effects, and/or death.
- At all times, Plaintiff's Decedent used the drug for its intended or reasonably - 40. foreseeable purpose.
- 41. Plaintiff's Decedent could not have discovered any defect in the drug through the exercise of care.
- 42. Defendants, as manufacturers of a prescription drug, are held to the level of knowledge of an expert in the field.

- 43. The warnings that were given by Defendants were not accurate or clear and/or were ambiguous.
- 44. Defendants had a continuing duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, of the potential risks and serious side effects associated with the use of Celebrex (Celecoxib).
- 45. As a proximate result of Defendants' failure to warn, Plaintiff's Decedent sustained harm, including, among other things, a heart attack, resulting in death.
- 46. Defendants made express representations to the consuming public at large through their aggressive marketing and advertising campaigns relative to their product, Celebrex.
- 47. Defendants, through their agents and/or sales representatives, made representations of the safety and efficacy of their product, Celebrex.
- 48. Celebrex does not conform to the express representations made through the Defendants' advertising and marketing efforts
- 49. Celebrex does not conform to the express representations made by Defendants' agents and/or sales representatives.
- 50. As a direct, legal, proximate and producing result of the express representations made by Defendants, through their advertising and marketing efforts, and by their agents and/or sales representatives, Plaintiff's Decedent sustained harm. Defendants' conduct in this matter was a contributing cause of Plaintiff's Decedent's heart attack, which resulted in death.
 - 51. Defendant's are "merchants" as defined in Alabama Code § 7-2-104.
 - 52. Celebrex (Celecoxib) is a "good" as defined Alabama Code § 7-2-105.
- 53. At the time that Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Celebrex (Celecoxib), Defendants knew of the intended, reasonably

foreseeable and/or ordinary use of Celebrex (Celecoxib) and impliedly warranted the drug to be of merchantable quality and safe and fit for such use.

- 54. Plaintiff's Decedent, in ingesting Celebrex (Celecoxib), reasonably relied upon the skill and judgment of Defendants as to whether Celebrex (Celecoxib) was of merchantable quality and safe and fit for its intended, reasonably foreseeable and/or ordinary use.
- 55. In breach of the implied warranty given by Defendants, Celebrex (Celecoxib) was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because the product was and is unmerchantable, in a defective condition and unreasonably dangerous and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was intended as described above.
- 56. In breach of the implied warranty given by Defendants, Celebrex (Celecoxib) was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because, among other things:
 - a. Use of Celebrex (Celecoxib) carried a risk of, among other things, a heart attack, stroke and/or death and other serious and life threatening side effects;
 - b. Defendants failed to include adequate warnings with the drug that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent,, of the potential risks and serious side effects of the drug;
 - c. Defendants failed to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the potential risks and serious side effects associated with the use of the drug.
- 57. As a direct, legal, proximate and producing result of Defendants' breach of warranty, Plaintiff's Decedent sustained substantial injuries including, among other things, a heart attack, resulting in death.

- Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented 58. to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, the safety and efficacy of the drug and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, material, adverse information regarding the safety and efficacy of Celebrex (Celecoxib).
- Defendants' misrepresentations were communicated to the medical, 59. pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, with the intent that they reach users and/or consumers of the drug, including Plaintiff's Decedent.
 - 60. Defendants either knew or should have known that the representations were false.
- Defendants made the misrepresentations and/or actively concealed information 6l. concerning the safety and efficacy of the drug with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, would rely on such in selecting Celebrex (Celecoxib) as a pain reliever.
- 62. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Celebrex (Celecoxib) in its labeling, advertising, product inserts, promotional materials or other marketing efforts.
- 63. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent. Specifically, Defendants misrepresented to and/or actively concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, that:

- There had been insufficient studies regarding the safety and efficacy of the a. drug;
- The drug was fully and adequately tested, despite knowing that there had b. been insufficient or inadequate testing of the drug;
- Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious prothrombotic and allergic and/or skin reactions, including, but not limited to, adverse cardiovascular events and/or Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis;
- d. Defendants knew or should have known of reports of increased heart attacks, allergic and/or skin reactions and/or strokes associated with the use of the drug;
- Defendants knew or should have known of the greatly increased risk of e. developing heart attacks, allergic and/or skin reactions and/or strokes associated with use of Celebrex (Celecoxib); yet, despite this they were downplaying the risk of the drug.
- The misrepresentations of and/or active concealment by Defendants were 64. perpetuated directly and/or indirectly by Defendants, its sales representatives, employees, distributors, agents and/or detail persons.
- 65. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continued to misrepresent the potential risks and serious side effects associated with the use of Celebrex (Celecoxib). Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, about the potential risks and serious side effects associated with the use of Celebrex (Celecoxib) in a timely manner, yet they failed to provide such warning.
- 66. Plaintiff's Decedent justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Celebrex (Celecoxib) to Plaintiff's Decedent's detriment.

- As a direct, legal, proximate and producing result of the misrepresentations of 67. Defendants, Plaintiff's Decedent sustained substantial injuries including, among other things, a heart attack, resulting in death.
- Defendants negligently misrepresented or failed to exercise reasonable care in 68. representing to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, the safety and efficacy of the drug and/or negligently concealed or failed to exercise reasonable care by concealing and failing to disclose to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, material, adverse information regarding the safety and efficacy of Celebrex (Celecoxib).
- Defendants' misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent with the intent that they reach users and/or consumers of the drug, including Plaintiff's Decedent.
- Defendants made these misrepresentations and/or actively concealed information 70. concerning the safety and efficacy of Celebrex (Celecoxib) in its labeling, advertising, product inserts, promotional materials or other marketing efforts.
 - Defendants either knew or should have known that the representations were false. 71.
- Defendants knew or should have known that the misrepresentations and/or 72. omissions concerning the safety and efficacy of the drug would be relied upon by the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, in selecting Celebrex (Celecoxib) as a pain reliever.
- Defendants made these misrepresentations and actively concealed adverse 73. information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug,

including Plaintiff's Decedent. Specifically, Defendants misrepresented to and/or actively concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, that:

- a. There had been insufficient studies regarding the safety and efficacy of the drug;
- b. The drug was fully and adequately tested, despite the fact that there had been insufficient or inadequate testing of the drug;
- c. Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious adverse cardiovascular events, allergic and/or skin reactions and strokes:
- d. Defendants knew or should have known of reports of heart attacks associated with the use of the drug;
- e. Defendants knew or should have known of the greatly increased risk of heart attacks, strokes, life threatening allergic and/or skin reactions and/or death and other serious and life threatening side effects associated with the drug; yet, despite this was downplaying the risks of the drug.
- 74. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, their sales representatives, employees, distributors, agents and/or detail persons.
- 75. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continued to misrepresent the potential risks and complications associated with Celebrex (Celecoxib). Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff's Decedent, about the potential risks and serious side effects associated with the use of Celebrex (Celecoxib) in a timely manner, yet they failed to provide such warning.

- 76. Plaintiff's Decedent justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Celebrex (Celecoxib) to Plaintiff's Decedent's detriment.
- 77. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiff's Decedent sustained harm, including, among other things, a heart attack, resulting in death.

COUNT I - WRONGFUL DEATH

- 78. Plaintiff repeats and re-alleges each of the allegations contained in this Complaint.
- 79. Plaintiff brings this wrongful death count pursuant to Alabama Code §6-5-410.
- 80. As a direct and proximate result of the conduct of Defendants and/or the defective nature of the product as outlined above, Plaintiff's Decedent, William Randolph Hall, Jr., had a heart attack and died.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands and prays for such damages from Defendants as allowed by Alabama's wrongful death statute, together with his costs in this action.

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff and demands a trial by jury on all issues presented herein.

Signed this 3/5T day of August

_, 2003. }

W INKS III (IINO)

TERÉ L. BEASLEY (BEA020) NAVAN WARD, JR. (WAR062)

ANDY D. BIRCHFIELD, JR. (BIR006)

PAUL SIZEMORE (SIZ004)

GERALD B. TAYLOR, JR. (TAY026)

GRADY REEVES (REE042)

OF COUNSEL:

JINKS, DANIEL & CROW, P.C. Post Office Box 350 Union Springs, Alabama 36089 (334) 738-4225 telephone (334) 738-4229 facsimile

BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. Post Office Box 4160 Montgomery, Alabama 36103-4160 (334) 269-2343 telephone (334) 954-7555 facsimile

Grady Reeves CERVERA, RALPH & BUTTS Post Office Box 325 Troy, Alabama 36081 (334) 566-0116 telephone (334) 566-4073 facsimile

IN THE CIRCUIT COURT OF BULLOCK COUNTY, ALABAMA

WILLIAM RANDOLPH HALL, SR., as the Administrator of the Estate of WILLIAM RANDOLPH HALL, JR.

Plaintiff,

VS.

CIVIL NO: CV- 2005. 98

PFIZER INC: PHARMACIA CORPORATION: MONSANTO COMPANY: G.D. SEARLE, LLC; ROBERT VANDELUNE; SAMUEL

KLEMENT; JAMIE PEACOCK; BEN MCCLURKIN, ROD MCWHORTER; AND TIFFANY GUCKENBERY

Defendants.

SUMMONS

This service by certified mail of this summons is initiated upon the written request of Plaintiff's attorney pursuant to the Alabama Rules of Civil Procedure.

NOTICE TO:

JAMIE PEACOCK 1804 Choctaw Street Dothan, Alabama 36303

The Complaint, which is attached to this summons, is important and you must take immediate action to protect your rights. You are required to mail or hand-deliver a copy of a written Answer, either admitting or denying each allegation in the Complaint to,

> NAVAN WARD, JR. BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. Post Office Box 4160 Montgomery, Alabama 36103-4160

the attorney for the Plaintiffs. THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN THIRTY (30) DAYS FROM THE DATE OF DELIVERY OF THIS SUMMONS AND COMPLAINT AS EVIDENCED BY THE RETURN RECEIPT, OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT. You must also file the original of your Answer with the Clerk of this Court within a reasonable time afterward

DATED: 8/31/05

IN THE CIRCUIT COURT OF **BULLOCK COUNTY, ALABAMA**

WILLIAM RANDOLPH HALL, SR., as the Administrator of the Estate of WILLIAM RANDOLPH HALL, JR. Plaintiff,

*

*

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CIVIL NO. <u>CV- 2005</u>. 98 VS.

PFIZER INC., a Delaware Corporation; PHARMACIA CORPORATION, a Delaware Corporation; MONSANTO COMPANY, a Delaware Corporation; G.D. SEARLE, LLC, a Delaware Corporation; ROBERT VANDELUNE; SAMUEL KLEMENT; JAMIE PEACOCK;* BEN MCCLURKIN, ROD MCWHORTER;* AND TIFFANY GUCKENBERY And fictitious Defendants A, B, C and D being those persons, firms or corporations whose actions, inactions, fraudulent suppression, fraud, scheme to defraud and/or other wrongful conduct caused or contributed to the Plaintiff's injuries and damages, and whose true names and identities are presently unknown to the Plaintiff but will be substituted by amendment when ascertained,

TRIAL BY JURY IS REQUESTED

Defendants.

PLAINTIFF'S FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS

Pursuant to Rule 33 and 34 of the Alabama Rules of Civil Procedure, the Plaintiff propounds the following interrogatories and requests for production of documents to be answered by Defendants Pfizer, Inc., Pharmacia Corporation, Monsanto Company, G.D. Searle, LLC., Robert Vandelune, Samuel Klement; Jamie Peacock; Ben McClurkin, Rod McWhorter and Tiffany Guckenbery, Party Defendants, in the manner and form prescribed by law:

Definitions

- 1. "Documents" shall mean writing of every kind, source and authorship, both originals and all non-identical copies thereof, in your possession, custody or control, or known by you to exist, irrespective of whether the writing is one intended for or transmitted internally by you or intended for or transmitted to any other person or entity, including, without limitation, any government agency, department, administrative entity or personnel. The term shall include handwritten, typewritten, printed, photocopied, photographic or recorded matter. It shall include communications in words, symbols, pictures, sound recordings, films, tapes and information stored in, or accessible through, computer or other information storage or retrieval systems, together with the codes and/or programming instructions and other materials necessary to understand and use such systems.
- 2. For purposes of illustration and not limitation, the term "Documents" shall include: correspondence, transcripts of testimony, letters notes, reports, papers, files, books, records, contracts, agreements, telegrams, teletypes and other communications sent or received, diaries, calendars, logs, notes or memoranda of telephonic or face-to-face conversations, drafts, work papers, agendas, bulletins, notices, circulars, inserts, announcements, instructions, schedules, minutes, summaries, notes and other records and recordings of any conferences, meetings, visits, statements, interviews or telephone conversations, bills, statements and other records of obligations and expenditures, canceled checks, vouchers, receipts and other records of payments, ledgers, journals, balance sheets, profit and loss statements, and other sources of financial data, analyses, statements, interviews, affidavits, printed matter (including published books, articles, speeches and newspaper clippings), press releases, charts, drawings, specifications, manuals, brochures and memoranda of all kinds to and from any persons, agencies or other entities.

- 3. "Identify", when used in reference to a person, means to state that person's full name, name of his or her employer, job title or position, and that person's last known residence and business addresses and telephone numbers.
- 4. Any reference to the word medicine, pharmaceutical, drug or product is intended to and shall mean those products known generally as "Celebrex (Celecoxib)" and any and all other trade names or trade marks under which "Celebrex (Celecoxib)" have been tested, sold or marketed.

Interrogatories

- 1. State the legal name of this Defendant, and the names and titles of all persons answering the following discovery on behalf of this Defendant.
- 2. State the relationship between this Defendant and any other Defendant in this lawsuit. Produce any documents that are evidence of such relationship.
- 3. Identify each employee or representative of this Defendant, or independent contractor, who had any responsibility for sales or marketing of Celebrex (Celecoxib) in Barbour County, Alabama. Intended to be included in the information sought by this interrogatory are the individuals responsible for sales and/or marketing on a statewide. regional and national level. This requests specific areas, with specific boundaries, i.e., counties, cities, south or north of specific highways, etc. which were included in each representative's sales territory.
- 4. State the revenue of this Defendant from the sale of Celebrex (Celecoxib)", both cumulatively and for each year since it was first marketed in the United States.
 - a. And, for each person identified in Interrogatory 3 above, please list all revenues directly or indirectly attributable to each person's sales/marketing efforts within their territorial region.

- 5. Identify each person, by name, current business and home address and telephone number, that is most knowledgeable about the following, substantive areas:
 - The development of Celebrex, specifically including, but not limited to its alleged COX-2 selectivity, or COX-2 specific qualities.
 - b. Presentation of investigative new drug application to the FDA.
 - c. Presentation of new drug application (NDA) to the FDA, including all scientific/pharmacological/toxicological information included therein, as well as all adverse reports.
 - d. The selection criteria for all study/investigative study patient participants, including each and every criteria considered for study participation.
 - e. Marketing of Celebrex internationally, nationally, regionally and within the State of Alabama, including, but not limited to, the frequency and context of all detail calls made within the State of Alabama, and by whom.
 - f. Training of inside and outside detail/sales representatives.
- 6. Identify each person whom you anticipate may testify as an expert witness in this action, and for each such person, state:
 - The subject matter on which the expert is expected to testify.
 - The substance of the facts and opinions to which the expert is expected to testify.
 - A summary of the grounds for each opinion.
 - d. All civil actions or other legal proceedings in which such person has testified, by deposition or at trial, since January 1, 1995, including for each action or proceeding the name of the case, the jurisdiction/court in which such action or proceeding is or was pending, the case number, name and address of opposing counsel, and whether the testimony was by deposition, at trial or other hearing, by affidavit or other sworn

declaration, or any combination of the foregoing. In addition, produce a current resume, curriculum vitae or similar other detailed statement of the person's background and qualifications.

- 7. What instructions were given to your sales representatives for providing information to physicians or responding to physician inquiries about the risks or potential risks associated with Celebrex?
- Did this Defendant prepare any information about Celebrex for direct dissemination to 8. the patient and/or his/her family, or for other direct advertising or marketing to consumers, including, but not limited to patient hand-out, instructions to doctors for answering patient inquiries, or videos? If so, please produce copies of these materials, and for each set of materials, state the date of initial preparations and the inclusive dates during which such materials were to be used.
- 9. State whether any cost-benefit or similar analyses were performed regarding Celebrex. If so, please produce copies of all documents reflecting or relating to any such analysis.
- Identify the names of the agencies, divisions, or committees or other groups within this 10. Defendant corporation that participated in the developing, manufacturing, distributing, and/or supplying of Celebrex, and identify and state the duties of all persons who served on these committees and/or agencies.
- 11. At any time prior to or during the development of Celebrex did this Defendant conduct tests or studies of any type, the results of which contain, or possibly contain, or reflect information relative to the possibilities of complications and/or adverse effects which have occurred in patients following the use of Celebrex? If so, please state:
 - a. The number of any such tests or studies.
 - b. An accurate description of the tests, prototypes, protocols and/or designs.

- c. The inclusive dates during which any and all such tests or studies were actually conducted.
- d. The test numbers of each and all such tests.
- The dates that the report of each such test or study was prepared.
- Describe in detail how each such test or study was conducted.
- g. Describe the results of all and each such tests or study with regard to information relative to the possibility of complications.
- h. Identify, for each test or study, all persons who conducted such test or study.
- The title or name of the test or study.
- 12. Explain in detail the records, which this Defendant keeps of consumer complaints that are made to it. Produce any and all copies of the complaints, regardless of the manner in which originally made, relating to Celebrex.
- 13. Give the name, address, and job title of the person employed or retained by this Defendant most familiar with maintaining the records of consumer complaints or adverse event reports that are made regarding Celebrex.
- 14. State the full extent of this Defendant's knowledge relating to the hazards, contraindications, side effects and adverse effects, reactions or events relating to the use of Celebrex.
- 15. Did this Defendant have specific and/or express knowledge of any adverse events (possibly, probably, or definitely causally related to Celebrex in the opinion of, or as concluded, determined, or diagnosed by the reporting source, i.e., reporting/prescribing/treating physician, any principal or co-investigator, not in the opinion, or as concluded, determined, or diagnosed by Defendant) related to Celebrex reported or received from any sources within, or outside the U.S., including but not

limited to, Japan, the Philippines, Great Britain, Australia, Europe, South America, Central America, North America or New Zealand at any time prior to the submission of the NDA for Celebrex?

This interrogatory includes, but is not limited to, any adverse event reports or information from foreign human Celebrex clinical trials, post-marketing reports or medical journals, seminars, letters, memos, correspondence, personal notes, e-mails or other forms of electronic data transmission. This request includes any information regarding adverse events which were potentially related to Celebrex, whether contained or included in the standard U.S. adverse event report form, or a similar form or method of reporting adverse drug events which are used in foreign countries, including but not limited to Japan, Australia, the Philippines, Great Britain, South America, Central America, North America, New Zealand or Europe.

- 16. Please state the date on which Celebrex was first marketed in any county, identifying country with date.
- 17. Please identify for this Defendant, for itself or any of its associated companies, divisions, officers and/or employees, all fines, sanctions, fees or penalty assessments of any type paid to any governmental agency or regulatory authority that in any manner relates to the development and marketing of any drug or pharmaceutical product. Your answer should include information identifying each such payment made by this Defendant, for itself or any of its associated companies, divisions, officers and/or employees from January 1, 1990 to the present, including the payee, the date of the payment, the amount and how such payment was identified or charged off in the Defendant's accounting records.
- 18. Identify by name, address, telephone number, and employer of each person who, on behalf of this Defendant, had any contact with employees of the FDA regarding

Celebrex. This interrogatory is intended to encompass and extend beyond a request for the names of employees of Defendant, and is specifically intended to include, but not be limited to, independent contractors and lobbyists that had <u>any</u> contact with the FDA regarding Celebrex, whether prior to, during the pendency of, or subsequent to the submission of the NDA relative to Celebrex.

- 19. Identify by name, address, telephone number, and employer each person who, on behalf of this Defendant, had <u>any</u> contact with members of Congress or the Senate, or any individual on a Congressperson's or Senator's paid or volunteer staff regarding Celebrex. This interrogatory is intended to encompass and extend beyond a request for the names of employees of Defendant, and is specifically intended to include, but not be limited to, independent contractors and lobbyists that had <u>any</u> contact with members of Congress or the Senate, or any individual on a Congressman's or Senator's paid or volunteer staff, regarding Celebrex, whether prior to, during the pendency of, or subsequent to the submission of the NDA relative to Celebrex.
- 20. Identify by name, address, telephone number, and employer each person who, on behalf of this Defendant, had <u>any</u> contact with members of the Health Care Financing Administration (HCFA) regarding Celebrex. This interrogatory is intended to encompass and extend beyond a request for the names of employees of Defendant, and is specifically intended to include, but not be limited to, independent contractors and lobbyists that had <u>any</u> contact with members if the Health Care Financing Administration (HCFA) regarding Celebrex, whether prior to, during the pendency of, or subsequent to the submission of the NDA relative to Celebrex.

- 21. Give the name, address, and job title of the person employed or retained by this Defendant most familiar with maintaining any and all post-marketing studies, whether initiated, funded or conducted by this Defendant or some other source or entity.
- 22. For each clinical study and/or protocol that was performed in reference to Celebrex by or on behalf of Defendant G.D. Searle, LLC, Pharmacia Corporation, Monsanto Company, or Pfizer, Inc., or any related entity of these Party Defendants, please provide:
 - a. the name, designation or other identifying information about the clinical study/protocol;
 - b. whether the said clinical study/protocol was published;
 - c. if said clinical study/protocol was published, where was it published (what journal) and when was it published?

Requests for Production

Plaintiffs specifically request that this Defendant produce the following:

- 1. The protocol(s) established by Defendant G.D. Searle, LLC, Pharmacia Corporation, Monsanto Company, or Pfizer, Inc., for the clinical testing of Celebrex.
- 2. The written procedures established by Defendant at any time during the development and marketing of Celebrex to address reports Defendant or others received from clinical trials or post-marketing experience concerning:
 - Any abnormal kidney function tests. a.
 - Any other indicators concerning kidney toxicity. b.
 - c. Any reports of renal failure.
 - d. Any reports of congestive heart failure.
 - e. Any reports of gastrointestinal bleeding/hemorrhage.

- Any reports of other bleeding/hemorrhage. f.
- Any reports of death. g.
- h. Any reports of precipitous increases in systemic blood pressure.
- Any reports of "myocardial infarctions" (MI). i.
- Any reports of "cerebrovascular accidents" (CVA). j.
- k. Any reports of allergic and/ or skin reactions.
- The protocols, procedures and guidelines that were employed by Defendant at any time 3. during the clinical trials and post-marketing experience with respect to how the Defendant responded or was to respond to reports received form:
 - Consumers. a.
 - b. Health professionals.
 - Others. c.
- 4. Records sufficient to identify each and every patent holder of the drug marketed as Celebrex by name, address, the patent number, the manner in which Celebrex is utilized in such patent.
- 5. Each and every contract between this Defendant, other patent holders or others regarding the development, manufacturing and marketing of the drug Celebrex.
- 6. Copies of all advertising text – whether printed, published on the web, radio, television or otherwise – concerning the drug Celebrex that was addressed to:
 - Physicians. a.
 - b. Pharmacists.
 - Consumers in English text. c.
 - d. Consumers – in Spanish or any other foreign language text.

- 7. The Defendant's records of account that demonstrate the costs incurred or otherwise paid by the Defendant in the development of the drug Celebrex. These costs are to be itemized by line item in the manner in which the Defendant accounted internally for its costs and not summarized in any manner beyond those totals or sub-totals created in the Defendant's accounting records.
- 8. The Defendant's records of account that demonstrate the costs incurred or otherwise paid by the Defendant in conducting its clinical trials of Celebrex.
- 9. The Defendant's records of account that demonstrate the costs incurred or otherwise paid by the Defendant in presenting the drug Celebrex to the Federal Drug Administration. This request includes, but is not limited to, all costs incurred or otherwise paid by the Defendant to apply for "fast track" status, to present information to the advisory panel(s), to hire consultants (including counsel) or representatives and other incidental costs.
- 10. All adverse reports maintained by the Defendant regarding Celebrex.
- 11. The complete records of each investigation conducted by the Defendant, or on behalf of the Defendant, in response to the reports responsive to Request for Production 10 above.
- 12. True and complete copies of all press releases and public statements made by the Defendant or on its behalf with regard to Celebrex from its inception to the present.
- 13. True and complete copies of the transcripts of any/all statements and appearances made by or on behalf of this Defendant before the Federal Drug Administration concerning Celebrex.
- 14. True and complete copies of the records of all proceedings of the FDA – whether advisory panel or otherwise - concerning Celebrex that are in the possession of Defendant or its agents.

- The complete text of all drafts and final versions of the product information leaflets or 15. brochures that were intended for publication or other distribution to doctors, pharmacists and/or consumers concerning Celebrex.
- 16. The complete text of all drafts and final versions of correspondence that Defendant directed to physicians concerning Celebrex from its inception to the present.
- The complete text of all drafts and final versions of statements that Defendant has made 17. to its stockholders concerning the development and marketing of Celebrex, any adverse effect reports and/or any FDA mandated warnings that were to accompany Celebrex.
- The Defendant's records showing its projection of sales of the drug Celebrex in any and 18. all markets. These records are to be produced in the most detail accumulated by Defendant in the ordinary course of business
- The Defendant's records showing the actual sales of the drug Celebrex in any and all 19. markets. These records are to be produced in the most detail accumulated by Defendant as well as any summaries of that data, kept in the ordinary course of business.
- All insurance agreements or policies under which a person transacting insurance may be 20. liable to satisfy part or all of a judgment which may be entered in this civil action or to indemnify or reimburse for payments made to satisfy the judgment. It is further requested that a verified or attested copy of the declaration sheet relating to any of the aforementioned insurance policies also be produced.
- 21. All documents or records of the Defendants relating to any advertisements for Celebrex, whether in professional journals or not.
- 22. All documents concerning any warnings, instructions for use, or other matters concerning the use and/or consumption and possible health risks regarding Celebrex.

- 23. All correspondence and documents evidencing any communication, in any form between or among any and all of the Defendants concerning Celebrex.
- 24. All drafts of documents containing instructions or warnings for the ultimate consumers of Celebrex. (For each such document, state the effective date or inclusive dates for distribution of use of such instructions or warnings.)
- 25. All documents concerning any changes, modification, alteration, and/or reformation of Celebrex, including changes to product packaging and product inserts.
- 26. All documents of the Defendants showing quality control, testing, analysis and health studies such as indications, contradictions, side effects, interactions, and adverse experiences, effects, or events concerning Celebrex.
- 27. All agreements entered into between or among any of the defendants.
- 28. All published literature in the possession of the Defendant concerning Celebrex.
- 29. Any documents of which Defendant has knowledge of concerning or relating to the adverse reactions, experiences, effects or events regarding Celebrex.
- 30. All documents relating to adverse reaction, experiences, effect or event reports as well as investigations of the same, including all notes, memos, letters, reports, files, articles, or any written or computer generated or stored information from any person or source whatsoever, authored as a consequence of the result of any such investigation which discusses, relates or concerns the adverse reaction of Celebrex.
- 31. All documents sent to the FDA regarding Celebrex.
- 32. All documents received from the FDA concerning Celebrex.
- 33. Copies of any warnings, precaution, informational letters, promotions, detail ads, which discuss Celebrex. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)

- Copies of all 10K's filed by or concerning this Defendant from 1990 through the present. 34.
- Copies of all annual reports to shareholders of this Defendant from 1990 through the 35. present.
- Copies of all package inserts for Celebrex. (For each such document, state the effective 36. date or inclusive dates for distribution or use of such document.)
- Copies of all documents which indicate, discuss or show the following: 37.
 - Gross sales of this Defendant, cumulatively and/or for each year since Celebrex 1. was first marketed in the United States.
 - 2. Gross sales for Celebrex, cumulatively and/or for each year since Celebrex was first marketed in the United States.
- Please identify the full names and corporate titles and addresses of the employees of this 38. Defendant having the most significant responsibilities for the development, licensing and marketing of Celebrex, and as to each such person, state the job titles, the inclusive dates during which such person held that job title, and describe briefly the area of responsibility with respect to Celebrex.
- Please provide the text of any and all warnings or instructions to physicians and/or 39. patients and consumers about the adverse effects in connection with Celebrex, and explain in detail any variation in terminology regarding side effects, contraindications, precautions and warnings. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)
- 40. Any and all studies regarding the safety and effectiveness of Celebrex.
- 41. All reports and other documents provided to the FDA or other governmental organization regarding complications, contraindications, hazards, side effects, or adverse experiences,

- effects or events from the use of Celebrex, whether used as monotherapy or in conjunction with any other therapy.
- Provide a detailed privilege log of all documents that have been removed from any file or 42. not produced because of a claimed privilege, work product doctrine, trade secret or confidential business information, or other privilege or basis for nondisclosure. Identify each document with such specificity that Plaintiff may fashion a particularized motion to compel as to each non-disclosed document.
- If this Defendant has relied upon or referred to any document in answering any 43. interrogatory, please attach copies of each such document to your answers.
- Documents reflecting the exact total number of patients worldwide, including but not 44. limited to those in Japan, the U.S., the Philippines, Australia, Great Britain, Europe, South America, Central America, North America and New Zealand, which Defendant determined, concluded, acknowledges, admits, concedes, or in its own opinion, believes or suspects, died from or suffered myocardial infarction, cerebrovascular accidents, allergic and or skin reactions, or internal bleeding, caused by Celebrex from the date the NDA for Celebrex was submitted to the FDA on, through and including the date of this Defendant's response to this discovery.

This includes deaths which occurred during human clinical trials or during the postmarketing period in any foreign country including, but not limited to, the Philippines, Australia, Great Britain, Europe, South America, Central America, North America and New Zealand. This includes any patients who were withdrawn from any clinical trial for any reason, medical or otherwise, whether or not the Defendant believes the injury or deaths as causally related to Celebrex.

- 45. A copy of the entire patient case study file and medical records, including autopsy reports, for each death case included in the response to the preceding request (#44), including the patient study number.
 - This request does not include any personal identification information about each patient.

 Please redact names, addresses, dates of birth, social security numbers, etc., so as to not violate the patient privacy or physician-patient privilege.
- determined, concluded, acknowledges, admits, concedes, or in its own opinion, believes or suspects experienced any adverse events, including, but not limited to, death, myocardial infarction, cerebrovascular accidents, allergic and/ or skin reactions, hypertension or increased hypertension, or gastro intestinal or esophageal bleeding, as a result of Celebrex at any time from the date of the first human Celebrex clinical trials and post-marketing experience, whether conducted in the U.S. or abroad, including but not limited to Japan, Great Britain, the Philippines, Australia, Europe, South America, Central America, North America and New Zealand to the date of this request which were reported to the FDA in the IND/NDA for Celebrex.

This includes any patients who were withdrawn from any clinical trial for any reason-medical or otherwise, whether or not Defendant believes the abnormalities were causally related to Celebrex.

47. A copy of the entire patient study file and medical records for each patient identified in the preceding request (#46) who were reported to the FDA in the IND/NDA to Celebrex.

This request does not include any personal identification information about the patients.

Please redact names, addresses, dates of birth, social security numbers, etc., so as to not violate the patient privacy or physician-patient privilege.

- 48. Documents reflecting the total number of clinical trial patients who began each separate human Celebrex clinical study, including, but not limited to those within the U.S., Japan, Great Britain, the Philippines, Australia, Europe, South America, Central American, North America and New Zealand who were withdrawn from the study or did or did not complete it for any reason, regardless whether or not Defendant believes the reason for the withdrawal was not causally related to Celebrex. Please identify the patient study number of each patient who was withdrawn.
- 49. A copy of the entire patient case study file and medical records for each patient who was withdrawn or otherwise did not complete the clinical trial who is included in the preceding request (#47). This request does not include any personal identification information about the patients. Please redact names, addresses, dates of birth, social security numbers, etc., so as to not violate the patient privacy or physician-patient privilege.
- 50. All tangible and electronic correspondence sent to and received from any person involved in each separate clinical trial study for Celebrex worldwide, including, but not limited to, the U.S., Japan, the Philippines, Australia, South America, Central America, North America and New Zealand, including, but not limited to, principal investigators, co-investigators, co-investigators, sub-investigators, technicians, their staff or any other person who in any way participated in the clinical trials. This includes, but is not limited to, any and all letters, reports, e-mails or any other source tangible data transmission, whether electronic or otherwise.

This includes, but is not limited to, adverse events, general observations of results during trials, preliminary study reports, or any other reference to results, problems, successes, general correspondence about Celebrex, observed during clinical trials.

- All tangible and electronic internal correspondence, person specific and/or general, including but not limited to, memos, e-mails, or other electronic data transmissions, to and from all sales and marketing personnel employed by, retained by, associated with or in any way affiliated with Defendant, which in any way discusses, relates to, or involves potential safety concerns with prescribing physicians and pharmacists, sales strategies, marketing and advertising regarding Celebrex.
- An entire copy of each and every Celebrex patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by or reported to Defendant prior to February 28, 2001, from any source, including, but not limited to, human Celebrex clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand which Defendant determined or concluded was definitely, probably, or possibly, not causally related to Celebrex and which was not included in the IND/NDA for Celebrex or reported or provided to the FDA thereafter through the date of this request.
- An entire copy of each and every Celebrex patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by, or reported to Defendant, from any source, including, but not limited to, human Celebrex clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand, which Defendant determined was definitely, probably, or possibly, not causally related to

- Celebrex and which was <u>not</u> reported or provided to the FDA thereafter through the date of this request.
- An entire copy of each and every Celebrex patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by, or reported to Defendant, from any source, including, but not limited to, human clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand, which Defendant determined was definitely, probably, or possibly causally related to Celebrex and which was not included in the IND/NDA for Celebrex, or reported to the FDA thereafter through the date of this request.
- An entire copy of each and every Celebrex patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by, or reported to Defendant from any source, including, but not limited to, human Celebrex clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand, which Defendant determined was definitely, probably, or possibly causally related to Celebrex and which was reported to the FDA thereafter through the date of this request.
- Any and all internal memos, internal or external correspondence and e-mails, including, but not limited to, any form of electronic data transmission to, or from Defendant, including, but not limited to, any employee, agent, director, officer or other personnel under the direct control of Defendant, to, or from, any other personnel, including, but not limited to, any persons involved in the clinical trials for Celebrex, other clinical

researchers, physicians, patients, the FDA or any other regulatory agency, or any other Defendant herein, which in any way discuss, involve, or relate to the decision to market Celebrex, and specifically as a COX-2 selective NSAID medication. This includes all information generated from the date of the first report of adverse events in the U.S. or abroad, through the date of this request.

- 57. Any and all internal correspondence, memos and e-mail or other electronic data transmission, to the date of this request, to or from Defendant's sales and marketing staff and personnel, including, but not limited to, Celebrex drug sales representatives, detail personnel and their managers, which in any way relates to, involves, or discusses what information regarding adverse events, should or should not be provided to, or discussed with, prescribing physicians, pharmacists or clinical investigators or their staff.
- Any and all correspondence, memos, e-mails or other forms of electronic data transmissions, to or from any external source (i.e., generated by someone who is not an agent, servant, employee, director, officer or other personnel under the direct control of Defendant), including, but not limited to, principal investigators and their staff, prescribing physicians or pharmacies, which in any way discusses, involves or relates to specific adverse events or general patient health concerns related to Celebrex.
- 59. Any and all internal memos, correspondence, e-mails or other electronic data transmissions to or from any agent, employee, officer, director or other person under the direct control of Defendant, or acting for or on Defendant's behalf, which in any way discusses, involves, or relates to the Defendant's denial of, conscious refusal to concede, admit, conclude, acknowledge, or express any opinion, publicly or privately, that Celebrex caused any health problems or injuries.

- Occumentation of any and all direct, or indirect, compensation paid to any principal or co-investigators, their staffs, families, or any other persons associated with the clinical trial studies of Celebrex for any reason. This includes, but is not limited to, copies of direct cash payment vouchers, canceled checks, money orders, wire transfers, indirect compensation such as travel expenses, meals, entertainment, gifts or honorariums, and also including, but not limited to, any and all forms of valuable consideration including securities and equities in Defendant's company or any company legally associated or affiliated with Defendant's company, including, but not limited to, stock ownership, options, warrants, bonds or other securities, which the recipient realized a tangible economic value at the time of the receipt or thereafter.
- Documentation of any and all direct, or indirect, compensation paid to any physicians, their staffs, families, or any other persons associated with the clinical trial studies of Celebrex for any reason. This includes, but is not limited to, copies of direct cash payment vouchers, canceled checks, money orders, wire transfers, indirect compensation such as travel expenses, meals, entertainment, gifts or honorariums, and also including, but not limited to, any and all forms of valuable consideration including securities and equities in Defendant's company or any company legally associated or affiliated with Defendant's company, including, but not limited to, stock ownership, options, warrants, bonds or other securities, which the recipient realized a tangible economic value at the time of the receipt or thereafter.
- A copy of all expenses related to travel and entertainment (as defined by the applicable Internal Revenue Code Section) paid by Defendant directly, or indirectly, to, or on behalf of any clinical investigation personnel, their staff or families, associated with the clinical trial studies of Celebrex. This includes, but is not limited to, payment for any and all

expenses related to seminars conducted or sponsored, in whole or in part, by this Defendant, its wholly owned subsidiaries, products, drugs or services; gratuitous tickets to entertainment events such as sporting events, arts, general entertainment (operas, plays, etc.), payment for meals, personal gifts or any other goods or services in which the recipient received an indirect economic benefit.

- A copy of the minutes of each and every committee meeting held by Defendant that in any way related to Celebrex, including, but not limited to, pre-marketing safety concerns, adverse events, marketing strategies, potential market penetration, potential profits, potential sales, strategies regarding how to respond to and deal with FDA concerns, strategies to persuade any person that adverse events related to Celebrex were not serious and should be dismissed, ignored or downplayed; package insert revision discussions, or any other subject matter related to the research, development, marketing, sales and safety concerns relating to Celebrex.
- 64. Any and all documentation of the account of the gross and net profits, including all incurred expenses, received by, and incurred by Defendant, relating to the sale and marketing of Celebrex worldwide. This specifically requests the Defendant's own accounting calculations of gross sales, expenses, net profits and other financial effects or impacts of Celebrex on Defendant's ongoing profits and operation, on an annual basis from 1999 to the date of this request.
- 65. All information sent by Defendant to pharmacies or drug distribution centers within the U.S. which in any way relate to, involve, or discuss Celebrex from January 1, 1998, through the date of this request. This includes, but is not limited to, letters, announcements, reports, original package inserts and all revisions, and adverse event

- reports. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)
- 66. A copy of all licensing agreements between this Defendant and any other entity relating to the research and development, production, distribution, sales and marketing, or other mutual involvement relating to Celebrex.
- 67. A copy of all marketing agreements between this Defendant and any other entity relating to the research and development, production, distribution, sales and marketing, or other mutual involvement relating to Celebrex.
- A copy of all profit sharing, expense sharing or other financial agreements between this Defendant and any other entity, relating to the research and development, production, distribution, sales and marketing, or other mutual involvement relating to Celebrex.
- 69. Any and all partnership agreements, joint venture agreements, co-development agreements, or other documented legal agreements between Defendant and any other entity regarding the research and development, distribution, sales and marketing or other involvement of Celebrex.
- 70. Any and all written settlement agreements with any plaintiff or claimants, whether based on pre-litigation claims or filed lawsuits relating to, or involving allegations that health related injuries were caused by Celebrex, whether within the U.S. or other foreign country.
- 71. The original petition(s) or complaint(s), including style, cause number and all plaintiffs or claimants of all lawsuits ever filed against Defendant relating to allegations that Celebrex caused injury or adverse events, whether in the U.S., or abroad.
- 72. Produce all memos, documents, tables, graphs, tests, test results or other illustrative or explanatory material by whatever name known or characterized by this Defendant in its

- normal course of business, which discusses or illustrates the relationship between COX-2 selectivity and therapeutic dosing.
- 73. Documents reflecting all epidemiological, clinical or double-blind placebo trial, test or study results that document or illustrate the relationship between COX-2 selectivity of Celebrex and therapeutic dosing levels.
- 74. Documents reflecting any and all post marketing surveys or studies completed by this Defendant regarding Celebrex whether or not the post marketing study or survey was undertaken, performed or funded by this Defendant.
- Any and all documents, letters correspondence, e-mail, facsimile, press release or other 75. written, verbal, electronic or other communication made by the Party Defendants, or any employee, agent, representative, independent contractor or otherwise, acting on their behalf, that was transmitted or communicated from the Party Defendants to any news industry or financial industry representative, or with the knowledge that the ultimate recipient would be a person acting for or on behalf of any person, firm or corporation within the news or financial industry. This request is intended to included, but not be limited to, all communications by or on behalf of Defendant and members of the print and broadcast news industry and the members of the financial industry; including, but not limited to, news, press or financial information; product launch information; or INDA/NDA information disseminated to ABC, NBC, CBS, CNBC, FOX, Fox News, The Wall Street Journal, Fortune Magazine, Money Magazine, any other financial or non-financial newspaper, periodical or publication, any bank, brokerage house/firm, or other financial institution or institutional investment corporation, whether for purposes of stock/bond underwriting, pursuant to financing conditions of underwriting or not, or for general dissemination of product news.

- Any post-Adenoma Prevention with Celecoxib (APC) revised label(s) or warnings 76. designed and/ or created after December, 2004, for the marketing of the drug Celebrex.
- For any individual identified in Interrogatory number 5, please provide complete 77. custodial files, which includes, but not limited to, internal and/or external documents, memorandums, correspondence, emails and/or any other form of electronic data transmission concerning Celebrex (Celecoxib).
- Please provide the complete custodial file in possession of Phillip Needleman and Mitch 78. Gandelman, which includes, but not limited to, internal and/or external documents, memorandums, correspondence, emails and/or any other form of electronic data transmission concerning Celebrex (Celecoxib).

ANDY D. BIRCHFIELD, JR.

NAVAN WARD, JR.

GERALD B. TAYLOR, JR.

PAUL SIZEMORE

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